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Healthcare Holdings (US) LLC*

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
OAKLAND DIVISION**

JASMINE SMITH and TAWNEYA  
HOUSER, individually and on behalf of all  
others similarly situated,

Plaintiffs,

v.

GLAXOSMITHKLINE CONSUMER  
HEALTHCARE HOLDINGS (US) LLC,

Defendant.

CASE NO. 4:21-cv-09390-JST

**DEFENDANT GLAXOSMITHKLINE  
CONSUMER HEALTHCARE HOLDINGS  
(US) LLC'S NOTICE OF MOTION AND  
MOTION TO DISMISS AMENDED  
COMPLAINT; MEMORANDUM OF  
POINTS AND AUTHORITIES IN  
SUPPORT OF MOTION TO DISMISS**

Date: Thursday, May 26, 2022

Time: 2:00 p.m.

Courtroom: Courtroom 6, 2nd Floor, United  
States District Court, 1301 Clay Street,  
Oakland, California

Judge: Judge Jon S. Tigar

Action Filed: December 3, 2021

**NOTICE OF MOTION AND MOTION**

**TO: THE ABOVE-CAPTIONED COURT AND ALL PARTIES AND THEIR COUNSEL  
OF RECORD:**

**PLEASE TAKE NOTICE** that on May 26, 2022, at 2:00 p.m., or alternatively, a date convenient to the Court, before Judge Jon S. Tigar in Courtroom 6, 2nd Floor, United States District Court, 1301 Clay Street, Oakland, California, defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (“GSK”) will move the Court, pursuant to Federal Rule of Civil Procedure 12(b)(6), to dismiss plaintiffs’ claims.

GSK’s Motion is based upon this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the pleadings and papers on file in this action and such further argument and matters as may be presented at the time of the hearing on this Motion.

DATED: March 25, 2022

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

By: /s/ Michael Minahan

MICHAEL MINAHAN  
Attorneys for Defendant

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1 The handful of superficial changes plaintiffs made to the Original Complaint in response  
 2 to GSK's motion to dismiss – including the addition of a second named plaintiff – do not come  
 3 close to curing the fundamental defects of the initial pleading. Although the Amended Complaint  
 4 has abandoned the most frivolous theory of liability previously advanced – i.e., that Abreva is  
 5 marketed as promising that it *will* (as opposed to *can*) shorten healing time for a cold sore to “2 ½  
 6 days” – the Amended Complaint still fails to plead a single plausible claim under California law  
 7 because there is nothing false or misleading about the challenged marketing materials, and they  
 8 are fully consistent with the FDA-approved labeling.

9 **First**, plaintiffs still fail to plausibly plead that the Abreva marketing was false or  
 10 misleading. Plaintiffs now allege that “Abreva cannot reliably heal cold sores in 2.5 days,  
 11 period.” (Am. Compl. ¶ 34.) But plaintiffs do not dispute the existence of clinical data upon  
 12 which the “2 ½ days” statement is based, instead alleging that Abreva's claims were based on  
 13 “flawed” studies. (*Id.* ¶ 47.) And an advertising claim is only false “if it has ‘actually been  
 14 disproved’” (e.g., with scientific evidence), *Kwan v. SanMedica Int'l, LLC*, No. 14-cv-03287-  
 15 MEJ, 2015 WL 848868, at \*4 (N.D. Cal. Feb. 25, 2010) (citation omitted), *aff'd*, 854 F.3d 1088  
 16 (9th Cir. 2017), a requirement that plaintiffs once again fail to plead given that none of the  
 17 “scientific studies” cited in the Amended Complaint purports to “disprove[]” (i.e., render  
 18 impossible) the notion that Abreva “can” shorten healing time to 2.5 days. Plaintiffs' theory that  
 19 GSK misrepresents that “*Nothing heals a cold sore faster*” than Abreva also fails as a matter of  
 20 law for multiple reasons, not the least of which is the presence of qualifying language directly  
 21 underneath the challenged statement, making clear that “Abreva® Cream contains the only non-  
 22 prescription ingredient approved by the FDA to shorten the time it takes to get rid of a cold sore.”  
 23 (Am. Compl. ¶ 26.) In other words, the only plausible message being conveyed is the truthful  
 24 statement that there is no other OTC ingredient that can shorten the duration of a cold sore. And  
 25 plaintiffs' final theory of misrepresentation – that GSK falsely promotes Abreva as providing  
 26 symptomatic relief and anti-viral benefits – is not based on any actual marketing statement.  
 27 Rather, all of the statements reinforce the central message of the FDA-approved packaging and  
 28 labeling that Abreva has been “PROVEN TO HEAL COLD SORES & SHORTEN THE

1 **DURATION** OF” symptoms (Am. Compl. ¶ 27 (emphasis added)), which plaintiffs have not  
2 plausibly pled is untrue.

3 **Second**, plaintiffs’ claims for common-law fraud, fraudulent concealment and violation of  
4 the UCL, CLRA and FAL separately fail because they are inadequately pled under Rule 9(b)’s  
5 heightened particularity standard. Although the Amended Complaint now includes the  
6 conclusory phrase, plaintiffs “saw, believed, and relied upon” (*see, e.g.*, Am. Compl. ¶ 22) in  
7 describing each piece of promotional material highlighted in the Amended Complaint, plaintiffs  
8 do not plead the particulars of that reliance – most notably, **when** and **where** they viewed the  
9 disparate promotional statements. Rather, plaintiffs have simply inserted conclusory statements  
10 of reliance in a half-baked attempt to address GSK’s arguments in the first motion to dismiss.  
11 Such barebones, formulaic allegations of reliance are still insufficient to survive a motion to  
12 dismiss.

13 **Third**, plaintiffs’ claims once again fail for an independent reason: they are expressly  
14 preempted by the federal Food, Drug, and Cosmetic Act (“FDCA”), which forecloses state-law  
15 claims challenging marketing that comports with FDA-approved labeling and findings of safety  
16 and effectiveness. After all, the Amended Complaint boils down to plaintiffs’ theory that Abreva  
17 is **not** “effective” for shortening the healing time of cold sores (Am. Compl. at pp. 15, 18, 19, 23),  
18 even though the FDA has “concluded that adequate information ha[d] been presented to  
19 demonstrate that the drug product *is* safe and effective for” that indication (*id.* ¶ 18). Because  
20 plaintiffs’ claims effectively seek to second-guess the FDA’s reasoned judgment that Abreva is  
21 safe and effective for the purpose of shortening cold sore healing time and the duration of  
22 symptoms and challenge marketing that is consistent with the FDA-approved labeling and  
23 packaging, they are preempted and should be dismissed for this reason as well.

24 Finally, dismissal should be with prejudice because the fundamental legal problems raised  
25 by GSK cannot be cured by amendment. Moreover, plaintiffs have now had two bites at the  
26 apple and still cannot plead viable claims. A third opportunity would be futile and improper.

**STATEMENT OF ISSUES TO BE DECIDED**

Whether plaintiffs have stated a cause of action in their Amended Complaint for any of their claims under California law and whether plaintiffs’ claims are preempted by federal law.

**BACKGROUND**

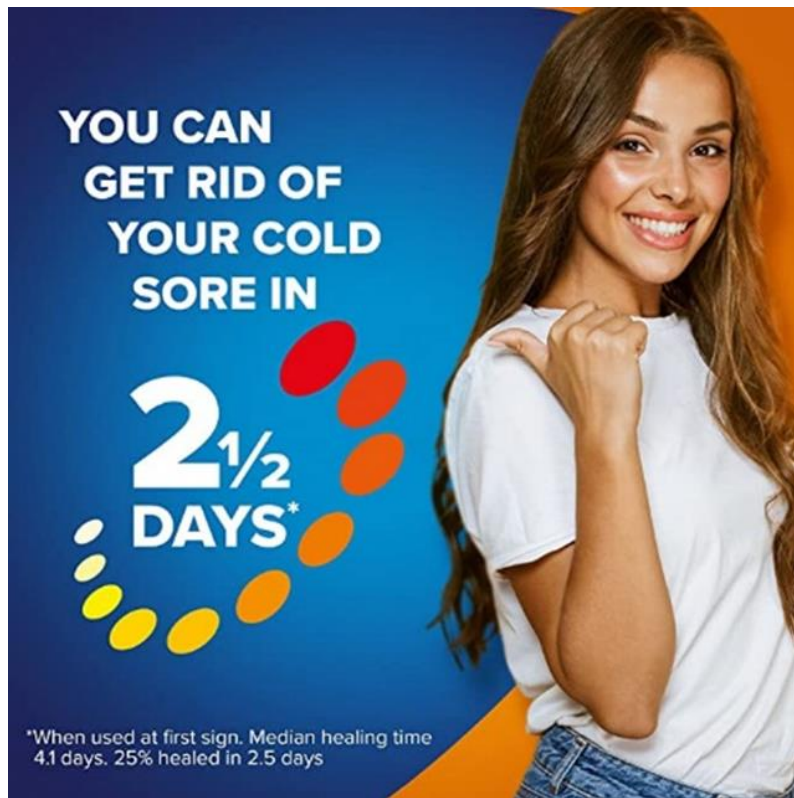
Cold sores, also known as fever blisters, are caused by the herpes simplex virus (“HSV”). (Am. Compl. ¶ 10.) HSV is not only “extremely common,” but “[o]nce infected, the virus remains in the body permanently, periodically causing” cold sores to form, usually on the lips. (*Id.*) Although there is no known cure for HSV, Abreva is an over-the-counter medication for treating cold sores. (*Id.* ¶¶ 12-13.) Abreva is a topical cream containing 10% of the active ingredient docosanol, which is “currently the only ingredient approved by the FDA to shorten healing time that is available without a prescription.” (*Id.* ¶ 13.) Abreva was originally developed by Avanir Pharmaceuticals (“Avanir”), which subsequently licensed exclusive rights for the sale and marketing of the medication to GSK. (*Id.* ¶ 14.)

In seeking FDA approval, Avanir relied on combined data from two clinical trials comparing 10% docosanol cream to polyethylene glycol (“EG”) placebo. (*Id.* ¶¶ 39-40; *see also id.* ¶¶ 13-14.) Although plaintiffs allege that the FDA “originally rejected” these studies in reviewing the Abreva New Drug Application (*id.* ¶ 15), Avanir appealed that decision and ultimately obtained approval of Abreva for the purpose of “shorten[ing] healing time and duration of symptoms” (*id.* ¶ 18 (quoting FDA Approval Letter at 1) (attached as Ex. 1)). Indeed, the Amended Complaint specifically recognizes that the FDA “concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text” (*id.* ¶ 18) – i.e., “***that the product shortens healing time and duration of symptoms.***” (FDA Approval Letter at 1 (emphasis added).)<sup>1</sup> Consistent with that approval, the front of the Abreva packaging (*see* Decl. of Jordan Schwartz (“Schwartz Decl.”) ¶¶ 2, 3, March 25, 2022; *see also* Am. Compl. ¶ 32) states that the medication

<sup>1</sup> The FDA Approval Letter is subject to judicial notice. *Eidmann v. Walgreen Co.*, 522 F. Supp. 3d 634, 642 (N.D. Cal. 2021) (taking judicial notice of information published on the FDA website because “[d]ocuments published on government-run websites are . . . reliab[le]”), *appeal dismissed*, No. 21-15659, 2021 WL 4785889 (9th Cir. May 17, 2021).

1 is the “only FDA Approved Medicine to Shorten Healing Time.”<sup>2</sup>

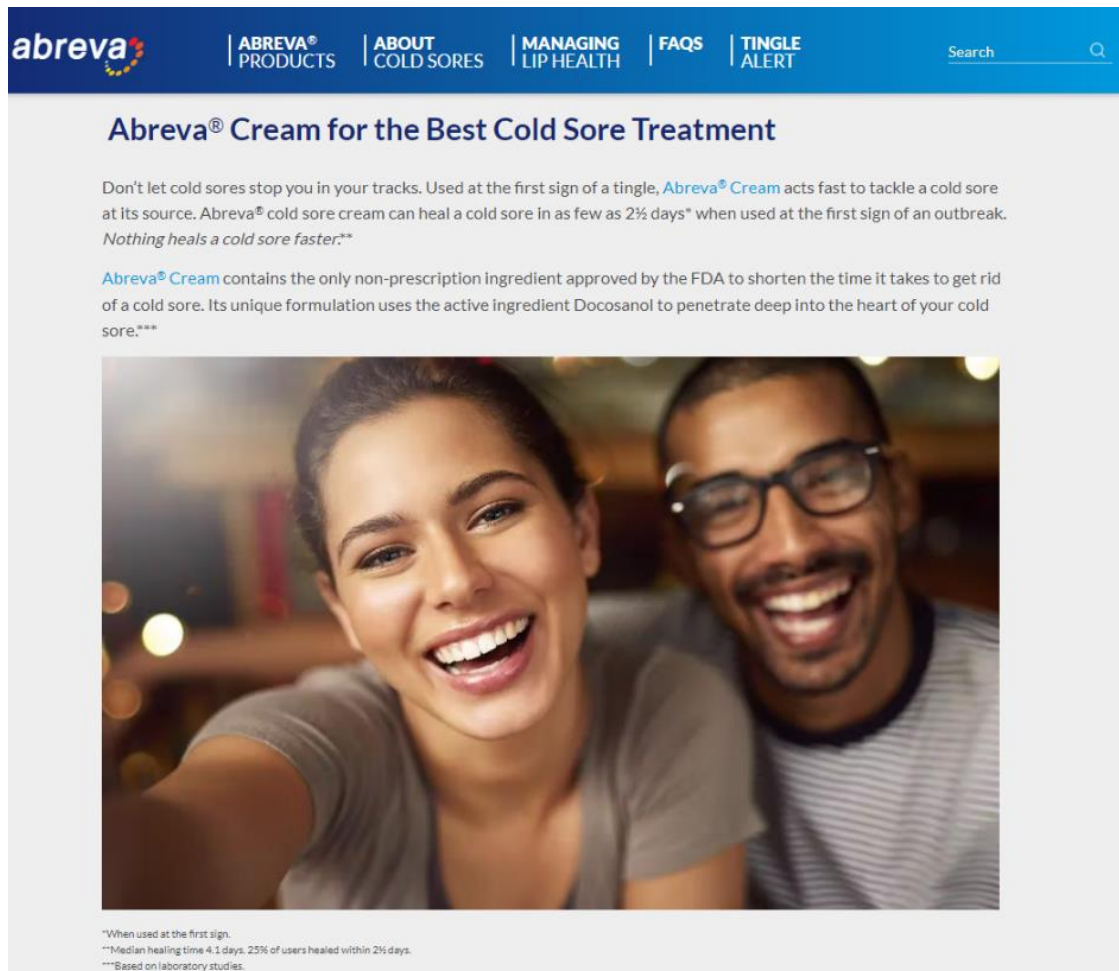
2 The Original Complaint alleged that GSK “overstepped the FDA’s approval” by making  
3 statements in advertisements and on its website that “Abreva *reduces* healing time to 2 ½ days.”  
4 (Orig. Compl. ¶¶ 18, 19 (emphasis added).) But each of the challenged statements is followed by  
5 an asterisk directing consumers to clarifying language *directly underneath* stating, “When used at  
6 first sign. Median healing time 4.1 days. 25% healed in 2.5 days.” (See, e.g., *id.* ¶ 22; see *id.*  
7 ¶¶ 23-25; see also Schwartz Decl. ¶¶ 5-8.)



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20 Presumably in response to GSK’s motion to dismiss, the Amended Complaint no longer  
21 claims that GSK represents that Abreva will heal a cold sore in “2 ½ days.” Rather, “Plaintiffs’  
22 contention is that Abreva cannot reliably heal cold sores in 2.5 days, period.” (Am. Compl. ¶ 34  
23 (“Plaintiffs’ contention is that Abreva cannot reliably heal sold sores in 2.5 days for  
24 anyone . . .”).)

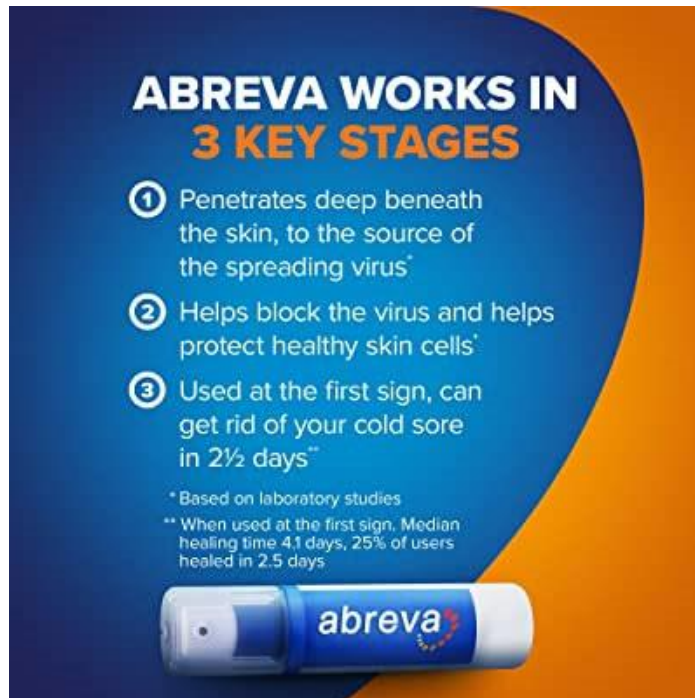
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28 <sup>2</sup> The packaging and labeling are “central” to plaintiffs’ claims and thus also subject to  
judicial notice. See *Eidmann*, 522 F. Supp. 3d at 642 (“[T]he labels are central to Eidmann’s  
claims [and subject to judicial notice] because it is the information conveyed on the Infants’  
Product packaging that Eidmann alleges was false or misleading.”).

The Amended Complaint also continues to allege that GSK “overstepped the FDA’s approval” by stating that “*Nothing heals a cold sore faster*” on “the home page of [defendants’] website.” (*Id.* ¶¶ 19, 26.) But this marketing statement (as depicted below) includes **multiple asterisks** pointing to the following clarifying information: (1) “When used at first sign”; (2) “Median healing time 4.1 days. 25% of users healed within 2 ½ days”; and (3) “Based on laboratory results.” See <https://www.abreva.com>. (See also Schwartz Decl. ¶ 8; Am. Compl. ¶ 26.) In addition, the challenged representation is immediately followed by the statement: “Abreva® Cream contains the only non-prescription ingredient approved by the FDA to shorten the time it takes to get rid of a cold sore.” See <https://www.abreva.com>. (See also Schwartz Decl. ¶ 8.)



Plaintiffs also point to a handful of other promotional statements from various retailer websites (e.g., Amazon). One of these ads promotes Abreva as “PROVEN TO HEAL COLD

1 SORES & SHORTEN THE DURATION OF” pain, itching, burning and tingling (shown below),  
 2 mirroring the information contained in the FDA-approved packaging. (See Am. Compl. ¶ 27; *see*  
 3 *also* Schwartz Decl. ¶ 9.) The other states that Abreva “Penetrates deep beneath the skin, to the  
 4 source of the spreading virus”; and “Helps block the virus and helps protect healthy skin cells.”  
 5 (Am. Compl. ¶ 25; *see also* Schwartz Decl. ¶ 7.) Both images are set forth below:



1 Finally, plaintiffs challenge three “commercials” related to Abreva. The first one answers  
 2 the question, “HOW TO GET RID OF YOUR COLD SORE”; the second states that Abreva  
 3 “PENETRATES DEEP INTO THE SKIN AND STARTS TO WORK IMMEDIATELY TO  
 4 BLOCK THE VIRUS”; and the third portrays a woman with a cold sore and the words “UPSET”  
 5 and “ANXIOUS” on her right and left cheeks, respectively, and features a narrator repeating the  
 6 “2 ½ days” statement, displaying the qualifying language discussed previously. (*See* Am. Compl.  
 7 ¶¶ 28-31.)

8 According to the Amended Complaint, the marketing summarized above is false or  
 9 misleading because it is based on Avanir’s “flawed studies” (*id.* ¶ 47); certain researchers have  
 10 offered “other explanations for the outcome of the studies” that supported the FDA’s approval  
 11 decision or have conducted research questioning the efficacy of topical cold sore treatments (*id.*  
 12 ¶ 48; *see also id.* ¶¶ 50-53); and some consumers have “expressed dissatisfaction about  
 13 [Abreva’s]” alleged “ineffectiveness” (*id.* ¶ 54). Based on these allegations, the original plaintiff,  
 14 Jasmine Smith, and a new plaintiff, Tawneya Houser, have filed an Amended Complaint on  
 15 behalf of a putative nationwide class action, asserting claims for: (1) violation of California’s  
 16 Unfair Competition Law (“UCL”); (2) violation of California’s Consumers Legal Remedies Act  
 17 (“CLRA”); (3) violation of California’s False Advertising Law (“FAL”); (4) violation of  
 18 California’s Song-Beverly Consumer Warranty Act; (5) breach of express warranty; (6) breach of  
 19 the implied warranty of merchantability; (7) fraudulent misrepresentation; (8) negligent  
 20 misrepresentation; (9) fraud by omission; and (10) unjust enrichment. (*See id.* ¶¶ 126-232.)

## 21 ARGUMENT

22 In order “[t]o survive a motion to dismiss [for failure to state a claim], a complaint must  
 23 contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its  
 24 face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S.  
 25 544, 570 (2007)). The “plausibility standard . . . asks for more than a sheer possibility that a  
 26 defendant has acted unlawfully.” *Id.* Rather, a “claim has facial plausibility when the plaintiff  
 27 pleads factual content that allows the court to draw the reasonable inference that the defendant is  
 28 liable for the misconduct alleged.” *Id.* A court should not accept “legal conclusion[s] couched

as . . . factual allegation[s]” or “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.” *Id.* (citation omitted). In addition, “[w]hen an entire complaint . . . is grounded in fraud and its allegations fail to satisfy the heightened pleading requirements of Rule 9(b), a district court may dismiss the complaint.” *Tabler v. Panera LLC*, No. 19-CV-01646-LHK, 2020 WL 3544988, at \*5 (N.D. Cal. June 30, 2020) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1107 (9th Cir. 2003)). Specifically, a plaintiff must plead “‘the who, what, when, where, and how of the misconduct charged,’ as well as ‘what is false or misleading about [the purportedly fraudulent] statement.’” *United States ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (alteration in original) (citation omitted). As set forth below, plaintiffs’ claims should be dismissed under these standards for multiple reasons.

**I. PLAINTIFFS’ CLAIMS FAIL BECAUSE THEY DO NOT PLAUSIBLY ALLEGE A MISREPRESENTATION OR BREACH OF ANY PROMISE.**

All of plaintiffs’ claims should be dismissed because they do not allege an actionable misrepresentation. Claims for common law fraud, fraudulent concealment and negligent misrepresentation require allegations of “fraudulent deception” – i.e., that the challenged statements “must be actually false.” *In re Actimmune Mktg. Litig.*, No. C 08-02376 MHP, 2009 WL 3740648, at \*7 (N.D. Cal. Nov. 6, 2009) (“A [common law] fraudulent deception must be actually false, known to be false by the perpetrator and reasonably relied upon by a victim who incurs damages.”) (alteration in original) (citation omitted), *aff’d*, 464 F. App’x 651 (9th Cir. 2011); *Wadhwa v. Aurora Loan Servs., LLC*, No. CIV. 2:10-3361 WBS DAD, 2011 WL 590911, at \*3 (E.D. Cal. Feb. 10, 2011) (dismissing fraud claim where the plaintiff failed to allege anything “regarding the circumstances of the fraudulent statements or omissions [and] what was actually false or misleading about the statements”); *Campos v. Wells Fargo Bank, N.A.*, No. EDCV 15-1200 JVS (DTBx), 2015 WL 5145520, at \*6 (C.D. Cal. Aug. 31, 2015) (dismissing negligent misrepresentation claim where the plaintiff “allege[d] no additional contextual facts to indicate that the statement was actually false”).

Similarly, to state a claim for violation of the FAL, CLRA or the fraud prong of the UCL, a plaintiff must allege a statement that would be likely to mislead a reasonable consumer. *See, e.g., Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th Cir 2016) (“[C]laims under the California consumer protection statutes are governed by the ‘reasonable consumer’ test.”); *Sugawara v. Pepsico, Inc.*, No. 2:08-cv-01335-MCE-JFM, 2009 WL 1439115, at \*4 (E.D. Cal. May 21, 2009) (dismissing UCL, FAL and CLRA claims because consumers were “unlikely to [be] deceive[d]” by the statements); *McKinnis v. Kellogg USA*, No. CV 07-2611 ABC (RCx), 2007 WL 4766060, at \*5 (C.D. Cal. Sept. 19, 2007) (dismissing UCL, FAL and CLRA claims because packaging was “not deceptive”). When “unfair business practices alleged under the unfair prong of the UCL overlap entirely with the business practices addressed in the fraudulent . . . prong[] . . . , the unfair prong of the UCL cannot survive” if the fraud prong is dismissed. *Hadley v. Kellogg Sales Co.*, 273 F. Supp. 3d 1052, 1099 (N.D. Cal. 2017) (citation omitted). The same is true with respect to fraud-based claims asserted under the unlawful prong of the UCL. *See In re Actimmune*, 2009 WL 3740648, at \*15 (“Once again plaintiffs have couched their claims in fraud or deception only. For the reasons stated above under the other prongs, these allegations must fail.”).<sup>3</sup>

Plaintiffs’ claims under the Song-Beverly Consumer Warranty Act, for breach of express and implied warranty and for unjust enrichment – which are all rooted in the claim that “Abreva does not work as advertised” (Am. Compl. ¶¶ 166, 182, 188, 228) – also require allegations that the challenged marketing is not true. *See, e.g., Hawyuan Yu v. Dr Pepper Snapple Grp., Inc.*, No. 18-cv-06664-BLF, 2020 WL 5910071 (N.D. Cal. Oct. 6, 2020) (breach-of-warranty claims premised on theory of deception failed for same reason as UCL, FAL and CLRA claims); *Baltazar v. Apple, Inc.*, No. CV-10-3231-JF, 2011 WL 3795013, at \*4 (N.D. Cal. Aug. 26, 2011) (“To state a viable claim under California’s Song-Beverly Consumer Warranty Act, a plaintiff must plead sufficiently a breach of warranty under California law.”); *In re Actimmune*, 2009 WL

<sup>3</sup> According to the Amended Complaint, plaintiffs’ claim under the “unlawful” prong of the UCL is based on alleged violations of the CLRA, FAL, Song-Beverly Act and Magnuson-Moss Warranty Act (Am. Compl. ¶ 139), all of which are premised on the core allegation that “Abreva was not as efficacious as advertised.” (*Id.* ¶ 156 (CLRA); *see also id.* ¶ 166 (“Abreva does not work as advertised.”) (Song-Beverly); *id.* ¶ 174 (GSK allegedly “misrepresent[ed] to consumers that Abreva could heal cold sores in 2.5 days.”) (FAL).)

3740648, at \*16 (dismissing claim for unjust enrichment premised on underlying fraud because “plaintiffs have not specifically pled that defendants engaged in any ‘unjust’ fraudulent conduct”).

Plaintiffs’ theory of deceptive advertising plainly fails under these principles for several reasons.

**A. Plaintiffs Do Not Plausibly Allege That Abreva Cannot Shorten Healing Time To 2 ½ Days.**

Plaintiffs’ primary allegation is that “Abreva cannot reliably heal cold sores in 2.5 days, period.” (Am. Compl. ¶ 34; *see also id.* (“Said differently, the asterisk does not render Defendants’ statements any less deceptive because Plaintiffs’ contention is that Abreva cannot reliably heal cold sores in 2.5 days for anyone, regardless of how it is used.”).) This contention fails as a matter of law because 25% of those involved in the clinical trial on which the “2 ½ days” statement is based *did* heal within 2 ½ days (*see* Am. Compl. ¶¶ 22-25), meaning that Abreva *can* shorten healing time to just 2 ½ days. *See Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 938 (7th Cir. 2001) (affirming dismissal of consumer fraud claim where the statement that was made on the labeling was “completely true”).

Plaintiffs nevertheless allege that the data underlying the “2 ½ days” statement were “flawed” and that other scientific and medical studies and consumer reviews “[r]efute” the “2 ½ days” statement. (Am. Compl. ¶¶ 47-48, 54.) But plaintiffs’ attack on the studies supporting the “2 ½ days” statement (which were submitted to, and considered by, the FDA in approving the Abreva New Drug Application) is unavailing. “California law does not provide a private cause of action for claims that advertising lacks substantiation.” *Kwan*, 854 F.3d at 1096-97; *see also Tubbs v. AdvoCare Int’l, LP*, No. CV 17-4454 PSG (AJWx), 2017 WL 4022397, at \*5 n.1 (C.D. Cal. Sept. 12, 2017) (noting that this principle applies to “all causes of actions premised on a lack-of-substantiation theory,” including common-law fraud and other fraud-based claims). Rather, the authority to challenge the substantiation of advertising claims is generally vested in regulators, in order to “limit[] ‘undue harassment of advertisers.’” *Kwan*, 854 F.3d at 1097-98 (quoting *Nat’l Council Against Health Fraud, Inc. v. King Bio Pharms., Inc.*, 107 Cal. App. 4th

1 1336, 1345 (2003)); *see also Tubbs*, 2017 WL 4022397, at \*7 (“[C]laims premised on false  
 2 advertising . . . must be based on an allegation that a defendant’s representations were false, not  
 3 merely unsubstantiated.”). Thus, for a private plaintiff, it is not “enough to attack the  
 4 methodology of [a] [d]efendant’s study; ‘instead, [such a plaintiff] must allege facts affirmatively  
 5 **disproving** [the d]efendant’s claims.’” *Kwan*, 2015 WL 848868, at \*2, \*6 (emphasis added)  
 6 (citation omitted) (to be actionable, claim that underlying data are flawed must rest on a study  
 7 “that disproves [the] [d]efendant’s [advertising] claims” or allegation that the advertised benefits  
 8 “are categorically impossible to achieve”).

9 Although plaintiffs allege that scientific and medical studies “[r]efute” the challenged  
 10 claims regarding Abreva (Am. Compl. ¶¶ 48-53; *see also id.* ¶ 34 (“[S]cientific studies confirm  
 11 Plaintiffs’ position.”)), plaintiffs’ own description of those materials merely states that there may  
 12 be “other explanations for the outcome” of the clinical trial underlying the Abreva New Drug  
 13 Application (*id.* ¶ 48); that “Abreva may require 9 days to heal the area affected by the cold sore”  
 14 (*id.* ¶ 50); that “topical treatments [have] demonstrated limited efficacy and required multiple  
 15 applications over several days” (*id.* ¶ 51 (citation omitted); *see also id.* ¶ 52 (similar)); and that  
 16 n-docosanol is “inactive as [an] **antiviral** agent[]” (*id.* ¶ 53 (emphasis added)). Even under  
 17 plaintiffs’ own descriptions, this “evidence” does not support the inference that it is “categorically  
 18 impossible” for Abreva to shorten the healing time of a cold sore to 2 ½ days. *See Kwan*, 2015  
 19 WL 848868, at \*6; *see also Tubbs*, 2017 WL 4022397, at \*6 (“inapposite and inconclusive  
 20 studies ‘do not give rise to a plausible claim’” that defendant’s advertising is false) (citation  
 21 omitted).

22 Plaintiffs’ reliance on various negative consumer reviews (*see* Am. Compl. ¶¶ 54-116) is  
 23 even more misplaced. As this Court has explained, because “every large company can expect to  
 24 have some customer complaints,” their existence “does not sufficiently establish the veracity of  
 25 the allegations contained therein.” *Curry v. Yelp Inc.*, No. 14-cv-03547-JST, 2015 WL 7454137,  
 26 at \*6-7 (N.D. Cal. Nov. 24, 2015) (Tigar, J.) (citation omitted), *aff’d*, 875 F.3d 1219 (9th Cir.  
 27 2017); *see also In re Netflix, Inc. Sec. Litig.*, No. C04-2978 FMS, 2005 WL 1562858, at \*7 (N.D.  
 28 Cal. June 28, 2005) (stating same and finding that “the existence of such complaints fails to

render Netflix’s statements about its service false”). This is all the more true because **78 percent** of the 951 consumers who reviewed the medication on the Abreva website recommended the product, with **66 percent** giving Abreva the highest possible rating. *See* <https://www.abreva.com/cold-sore-products/abreva-reviews/>. Similarly, of the 415 users who posted reviews on drugs.com, 22% gave Abreva a 10/10. <https://www.drugs.com/comments/docosanol-topical/abreva-for-herpes-simplex.html>.<sup>4</sup> The fact that **some** customers were not satisfied with the product cannot support a claim that the product **never** works. In short, plaintiffs’ references to cherry-picked complaints by unnamed consumers do not support their claims that Abreva “cannot reliably heal cold sores in 2.5 days, period.”

**B. Plaintiffs’ Other Challenge Regarding Abreva’s Ability To Shorten Healing Time And Duration Of Symptoms Is Also Meritless.**

Plaintiffs also challenge a statement on the Abreva website stating that “*Nothing heals a cold sore faster.*” (Am. Compl. ¶ 26.) But as with the statement regarding “2 ½ days,” this representation includes the following clarification: “Median healing time 4.1 days. 25% of users healed within 2½ days.” (*Id.*) Moreover, as noted above, the challenged representation is immediately followed by the statement: “Abreva® Cream contains the only non-prescription ingredient approved by the FDA to shorten the time it takes to get rid of a cold sore.” *See* <https://www.abreva.com>. (*See also* Schwartz Decl. ¶ 8.) As a result, the message conveyed – given “the context of the entire” advertisement – is the entirely truthful statement that there is no other OTC ingredient that can shorten the duration of a cold sore. *Freeman v. Time, Inc.*, 68 F.3d 285, 289-90 (9th Cir. 1995) (“Any ambiguity that Freeman would read into any particular statement [regarding the sweepstakes] is dispelled by the promotion as a whole,” which explained that plaintiff would only win the money if he had the winning number).

Plaintiffs do not address this qualifying language in their Amended Complaint, much less plead how the “faster” statement is false or misleading, beyond recycling the statement in a

<sup>4</sup> The Court may take judicial notice of these statistics because they are set forth in the websites cited to and relied on in the Amended Complaint. *See Knieval v. ESPN*, 393 F.3d 1068, 1076-77 (9th Cir. 2005) (district court properly considered portions of a website other than those specifically alleged in the complaint as being defamatory under the “incorporation by reference” doctrine).

footnote from the Original Complaint that Luminance Red, an FDA-cleared device, “purports to heal cold sores in as few as 2.2 days,” and adding a new citation to an article supposedly “supporting the notion that products such as Luminance Red can heal cold sores in as few as 2.2 days.” (Am. Compl. ¶ 26 & n.5.) However, one manufacturer’s marketing claims about its own product are not capable of “affirmatively disproving” another manufacturer’s statement about an entirely different product. *See Kwan*, 2015 WL 848868, at \*2, \*6. Plaintiffs’ reliance on the article cited in their footnote is similarly unavailing because it compared diode laser therapy against acyclovir cream, *not* docosonal, which is the active ingredient in Abreva. (*See* Am. Compl. ¶ 26 & n.5.) *See Tubbs*, 2017 WL 4022397, at \*6 (“not only does this article indicate only a lack of substantiation and not outright falsity, it does not mention Defendant, Spark, or any other 24-Day Challenge product. Courts have previously found a reliance on studies that did not involve the products at issue to be insufficient in similar cases.”); *see also Eckler v. Wal-Mart Stores, Inc.*, No. 12-CV-727-LAB-MDD, 2012 WL 5382218, at \*6-7 (S.D. Cal. Nov. 1, 2012) (studies that did not involve the product at issue do not lend “facial plausibility” to claims that representations are false or misleading). In any event, neither the Luminance Red website nor the article cited by plaintiffs changes the pertinent fact that the challenged Abreva statement is being made with regard to *OTC “ingredients,” not devices*. Thus, plaintiffs’ reference to claims about an FDA-cleared device’s healing time also does not support a plausible claim of false or misleading representations.

**C. The Challenged Marketing Does Not Represent That Abreva Provides Either Symptomatic Or Anti-Viral Benefits.**

Plaintiffs finally reassert their theory that GSK has falsely represented that Abreva provides symptomatic and anti-viral benefits (Am. Compl. ¶¶ 1, 19), citing statements in various online advertisements that Abreva “[h]elps protect healthy skin cells” and “[s]hortens symptom durations” (*id.* ¶ 24; *see also* Schwartz Decl. ¶ 6); “[p]enetrates deep beneath the skin, to the source of the spreading virus” and “[h]elps block the virus and helps protect healthy skin cells” (Am. Compl. ¶ 25; *see also* Schwartz Decl. ¶ 7; *see also* Am. Compl. ¶ 27 (similar)). But none of these statements claims symptomatic or anti-viral benefits.

Courts routinely reject “misrepresentation” claims that are based not on the express language of the representation at issue, but rather the plaintiff’s subjective gloss on that language. *See, e.g., Werbel v. Pepsico, Inc.*, No. C 09-04456 SBA, 2010 WL 2673860, at \*5 (N.D. Cal. July 2, 2010) (claim that defendant represented that Cap’n Crunch cereal “contains berries” and “was a substantially fruit-based product deriving nutritional value from fruit” is “frivolous” because “[n]o such claim is made expressly or impliedly anywhere on the Cap’n Crunch packaging or marketing material cited by [p]laintiff”) (citation omitted); *Ebner*, 838 F.3d at 965-66 (affirming dismissal of claims based on contention that lip balm weight was misleading where not all product was accessible because the package contained “no . . . words, pictures, or diagrams . . . from which *any* inference could be drawn or on which *any* reasonable belief could be based about how much of the total lip product c[ould] be accessed”); *Bober*, 246 F.3d at 938 (affirming dismissal of consumer fraud claim where “[n]one of the statements” on the product labeling “expressly ma[de]” the claim underlying the plaintiff’s allegations).

Here, none of the cited statements suggests that Abreva provides symptomatic relief while the cold sore remains manifest. Instead, they claim, at most, to shorten the *duration* of cold sore symptoms, which is entirely consistent with the claims permitted by the FDA-approved labeling – i.e., that Abreva “shortens healing time and duration of symptoms: tingling, pain, burning, and/or itching.” (Schwartz Decl. ¶¶ 2, 3.) Nor do any of the cited statements make anti-viral claims. To be sure, the statements describe the mechanism of action by which Abreva penetrates the skin and “blocks” the virus from spreading further. But nothing remotely claims that Abreva destroys the herpes virus; nor would any reasonable consumer draw that conclusion from these statements, especially in light of the fact, so well-known that plaintiffs assert it without citation, that “there is no known cure for” the herpes virus. (Am. Compl. ¶ 12.)

For all of these reasons, plaintiffs’ claims that GSK’s marketing of Abreva is false or misleading are not plausibly pled and should be dismissed under Rule 12(b)(6).

## **II. PLAINTIFFS’ RELIANCE CLAIMS ARE NOT PLED WITH THE REQUISITE PARTICULARITY UNDER RULE 9(B).**

Plaintiffs’ common-law claims for fraud, fraudulent concealment, negligent

1 misrepresentation, unjust enrichment and for violation of the UCL, CLRA and FAL separately  
 2 fail because they are not pled with the requisite particularity under Rule 9(b).

3 Plaintiffs' common-law fraud and consumer-protection claims require concrete allegations  
 4 of reliance. *See, e.g., In re Arris Cable Modem Consumer Litig.*, No. 17-CV-01834-LHK, 2018  
 5 WL 288085, at \*6 (N.D. Cal. Jan. 4, 2018) ("[T]o state a claim under the UCL, FAL, and CLRA,  
 6 [plaintiff] must allege facts sufficient to show that she relied on the defendant's alleged  
 7 misrepresentation.") (citation omitted); *Myers-Taylor v. Ornuva Foods N. Am., Inc.*, No. 3:18-cv-  
 8 01538-H-MDD, 2019 WL 424703, at \*5 (S.D. Cal. Feb. 4, 2019) (noting that "justifiable  
 9 reliance" is an element of common-law fraud and negligent misrepresentation claims in  
 10 California); *Ahern v. Apple Inc.*, 411 F. Supp. 3d 541, 564 (N.D. Cal. 2019) ("For California  
 11 fraudulent concealment claims . . . '[r]eliance is an essential element . . . .'" (quoting *Sevidal v.*  
 12 *Target Corp.*, 189 Cal. App. 4th 905, 928 (2010))). In addition, causation is an essential element  
 13 of plaintiffs' claim for unjust enrichment. *Krouch v. Wal-Mart Stores, Inc.*, No. 12-cv-02217-  
 14 YGR, 2014 WL 5463333, at \*8 (N.D. Cal. Oct. 28, 2014) (Unjust enrichment claims require "a  
 15 sufficient causal nexus between an alleged injury and the conduct of the accused party such that  
 16 the accused party was unjustly enriched."). These elements must be pled with sufficient  
 17 particularity in light of the heightened pleading standard of Rule 9(b), which applies to plaintiffs'  
 18 common-law claims for fraud, concealment, negligent misrepresentation, unjust enrichment and  
 19 violation of California's consumer-protection statutes. *See, e.g., Kearns v. Ford Motor Co.*, 567  
 20 F.3d 1120, 1125 (9th Cir. 2009) ("[W]e have specifically ruled that Rule 9(b)'s heightened  
 21 pleading standards apply to claims for violations of the CLRA and UCL."); *Wang v. OCZ Tech.*  
 22 *Grp., Inc.*, 276 F.R.D. 618, 628 (N.D. Cal. 2011) (applying Rule 9(b) to UCL, CLRA, FAL,  
 23 negligent misrepresentation and unjust enrichment claims); *Andren v. Alere, Inc.*, 207 F. Supp. 3d  
 24 1133, 1140 (S.D. Cal. 2016) (CLRA, UCL, fraud and unjust enrichment claims "either allege  
 25 fraud or sound in fraud" and are therefore "subject to the heightened pleading standard of Rule  
 26 9(b)").

27 GSK previously argued that Ms. Smith did not allege that she saw any of the challenged  
 28 marketing before purchasing the product, much less tie any of it to her own decision to purchase

1 Abreva – and thus had not adequately pled reliance. In an apparent attempt to cure that defect,  
 2 the Amended Complaint now includes a new, identical phrase in each paragraph depicting and  
 3 summarizing a challenged piece of marketing: “As set out in the paragraph below, which  
 4 Plaintiffs saw, believed, and relied upon in making their purchases, Defendants prominently  
 5 claim . . . .” (Am. Compl. ¶¶ 22-31.)

6 Plaintiffs’ conclusory assertion that they “saw, believed, and relied upon” (*see, e.g.*, Am.  
 7 Compl. ¶ 22) every single promotional statement highlighted in the Amended Complaint “in  
 8 making their purchases” does not provide the requisite detail to survive a motion to dismiss.  
 9 *Kearns*, 567 F.3d at 1126 (affirming dismissal of UCL and CLRA claims under Rule 9(b) because  
 10 the plaintiff did not, *inter alia*, “specify when he was exposed to” the challenged television  
 11 advertisements and other promotional materials); *see also In re Volkswagen “Clean Diesel”*  
 12 *Mktg., Sales Pracs., & Prods. Liab. Litig.*, No. 3:17-cv-4372-CRB, 2019 WL 5698339, at \*1  
 13 (N.D. Cal. Nov. 4, 2019) (finding *Kearns* to be “controlling authority” and dismissing  
 14 “misrepresentation claims” because plaintiff “does not identify *when* and *where* she saw this  
 15 advertising”) (emphases added) (citation omitted).

16 Although the added language vaguely suggests that plaintiffs saw the challenged  
 17 marketing prior to purchasing Abreva, the Amended Complaint does not provide any details as to  
 18 “how long before the purchase” plaintiffs were exposed to – and supposedly relied on – that  
 19 marketing. *See Frenzel v. AliphCom*, 76 F. Supp. 3d 999, 1014-15 (N.D. Cal. 2014) (dismissing  
 20 UCL, CLRA and FAL claims because “like the *Kearns* plaintiff, Frenzel fails to allege with  
 21 sufficient particularity when he was exposed to the alleged misrepresentations”; “[t]he allegation  
 22 that he reviewed them before purchasing his Jawbone UP device is not enough, as there is no  
 23 indication as to how long before the purchase his review occurred”); *see also Wang*, 276 F.R.D.  
 24 at 628 (“Only by identifying the particular circumstances in which Wang viewed and relied upon  
 25 OCZ marketing materials does Wang meet the threshold pleading standard wherein the defendant  
 26 ‘can prepare an adequate answer from the allegations.’”) (citation omitted). Plaintiffs’ conclusory  
 27 allegations of reliance and causation also fail to specify where they were supposedly exposed to  
 28 the “bulletins on third-party websites such as Amazon, amongst other mediums.” (Am. Compl.

¶ 20.) *See Kearns*, 567 F.3d at 1126 (“Kearns failed to articulate the who, what, when, **where**, and how of the misconduct alleged.”) (emphasis added). Because plaintiffs’ own Amended Complaint makes clear that the so-called “bulletins” in question appear on multiple different websites and mediums, the onus was on them to specify which website(s) they visited in viewing the challenged marketing.

Plaintiffs’ failure to provide the requisite detail strongly implies that they cannot do so – i.e., that they did **not** both actually “s[ee], believe[], and rel[y] upon” each of the challenged statements identified in the Amended Complaint, which would have entailed an inordinate amount of research for an everyday drugstore purchase. The very purpose of Rule 9(b) is to ensure that claims sounding in fraud “are well grounded in fact,” and plaintiffs’ allegations suggest exactly the opposite. *See Corp. Printing Co. v. States News Serv.*, No. 93 CIV. 7296 (RPP), 1994 WL 9667, at \*1 (S.D.N.Y. Jan. 11, 1994) (dismissing fraud claim for failure to comply with Rule 9(b); “[d]ue to their potential for misuse,” courts are “reluctant to allow claims of fraud absent a showing that they are well grounded in fact”).

Nor can plaintiffs bypass Rule 9(b) by invoking the California Supreme Court’s holding that a plaintiff “is not required to necessarily plead and prove individualized reliance on specific misrepresentations or false statements where . . . those misrepresentations . . . were part of an **extensive and long-term** advertising campaign.” *In re Tobacco II Cases*, 46 Cal. 4th 298, 327-28 (2009) (emphasis added). As both this and other courts have recognized, the *Tobacco II* exception is “narrow” and only applies where a plaintiff has sufficiently alleged an advertising campaign of the “type” at issue in *Tobacco II*, which “involved a ‘**decades-long**’ campaign of the tobacco industry to conceal the health risks of its product while . . . simultaneously, engaging in ‘**saturation**’ advertising targeting adolescents.” *Haskins v. Symantec Corp.*, No. 13-cv-01834-JST, 2013 WL 6234610, at \*5 (N.D. Cal. Dec. 1, 2013) (Tigar, J.) (emphases added) (citation omitted); *Tabler*, 2020 WL 3544988, at \*8-9 (“the scope of *In re Tobacco II* is narrow,” highlighting the “pervasiveness and extent of any advertising campaign”); *Gutierrez v. Johnson & Johnson Consumer Inc.*, No. 19-CV-1345 TWR (AGS), 2021 WL 822721, at \*6 (S.D. Cal. Jan.

22, 2021) (“Plaintiffs’ claims do not fall within this narrow exception” because they “fail to establish a ‘long-term marketing campaign’ during the relevant class period.”).

Plaintiffs here have failed to plausibly allege a decades-long campaign of the sort at issue in *Tobacco II*. Although the Amended Complaint claims that GSK has engaged in an “aggressive long-term, decades long” marketing “campaign” (Am. Compl. ¶ 20), plaintiffs have merely identified a handful of current online promotional statements and commercials that are not remotely comparable to the “*saturation* advertising” at issue in *Tobacco II*. *Haskins*, 2013 WL 6234610, at \*5 (emphasis added) (“Plaintiff failed to allege a campaign of this type . . . .”) (quoting *In re Tobacco II*, 46 Cal. 4th at 327); *see also Tabler*, 2020 WL 3544988, at \*10 (rejecting plaintiff’s reliance on *Tobacco II* exception where the plaintiff “alleges she saw some unspecified advertisement and described a representative sample of possible advertisements”). Further, plaintiffs’ claim regarding the duration of the so-called marketing “campaign” cannot be reconciled with the allegation in the Original Complaint that GSK began making the “2 ½ days” statement in 2013. (Orig. Compl. ¶ 119.)<sup>5</sup>

In short, plaintiffs have failed to adequately plead causation/reliance with sufficient particularity, and their claims for fraud, fraudulent concealment, negligent misrepresentation, unjust enrichment and violation of the UCL, CLRA and FAL should be dismissed for this reason as well.

### III. PLAINTIFFS’ CLAIMS ARE PREEMPTED.

Plaintiffs’ claims should also be dismissed because they are preempted by federal law. “Congress has explicitly mandated that federal law pre-empts nearly all state-law claims relating to OTC medications.” *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 512 F. Supp. 3d 1278, 1296 (S.D. Fla. 2021), *appeal filed*. Specifically, section 379r(a) of the FDCA expressly preempts state-law claims that impose duties on companies marketing OTC products that are “different

<sup>5</sup> Even where an amended complaint is the operative complaint, courts may still credit admissions in a prior complaint. *See, e.g., In re Bang Energy Drink Mktg. Litig.*, No. 18-CV-05758-JST, 2021 WL 3277267, at \*4 (N.D. Cal. June 30, 2021), *appeal dismissed*, No. 21-16248, 2021 WL 6751859 (9th Cir. Nov. 12, 2021) (“These allegations, however, cannot be reconciled with the judicial admissions in Plaintiffs’ prior complaint that the Products do contain creatine.”).

from,” “in addition to,” or “otherwise not identical with” a federal requirement under the FDCA. 21 U.S.C. § 379r(a). “The touchstone of preemption under § 379r is the *effect* that a finding of liability on a particular claim would have on the [d]efendants, and not the particular common law or state law theory upon which that claim was brought.” *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1283 (C.D. Cal. 2008). Accordingly, “[c]ourts interpret § 379r’s ‘federal requirement’ pre-emption broadly,” *In re Zantac*, 512 F. Supp. 3d at 1296, foreclosing “even state-law advertising claims, provided the advertisements are based upon content approved by the FDA for a drug’s labeling,” *id.* (citing *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 400 (5th Cir. 1999)), “in addition to claims that would require additional warnings on labeling or in an advertisement,” *id.* (citing *Carter*, 582 F. Supp. 2d at 1282).

For example, in *Carter*, plaintiff consumers initiated several putative class actions against manufacturers of OTC cough and cold medications, alleging that the defendants knew or should have known that their products “‘[d]id not work’ and [were] dangerous to children under the age of six.” 582 F. Supp. 2d at 1276-77. The plaintiffs asserted claims for fraud, unjust enrichment, false and misleading advertising, fraudulent concealment and breach of warranty. *Id.* at 1277. Although an FDA Advisory Panel had previously examined evidence that OTC cough and cold medicines were unsafe and ineffective for children under six years of age and recommended that those products not be used in children within that age group, the FDA ultimately adopted the Panel’s recommendation for children *under the age of two*. *Id.* at 1276. The plaintiffs nonetheless alleged that the defendants’ marketing related to the safety and effectiveness of the OTC medications in children under six years of age was false because “OTC cough and cold medicines do not work and are dangerous to young children.” *Id.* at 1284. The court rejected this claim because the statements were “based entirely upon FDA-approved labeling and advertising, and explain[ed] the conditions under which the FDA ha[d] determined that OTC cough and cold medicine will be safe and effective.” *Id.* As such, the plaintiffs’ claims threatened to “impose liability upon [d]efendants for complying with FDA regulations, and constitute[d] perhaps the clearest example of state law requirements that differ from federal requirements.” *Id.* at 1285.

1 The same is true here. The Amended Complaint confirms that the gravamen of plaintiffs'  
 2 lawsuit is that Abreva and its main ingredient, docosanol, are “[n]ot [e]ffective” (Am. Compl. at  
 3 pp. 15, 18; *see also id.* at p. 19) – i.e., that they do not “improv[e] healing time whatsoever” (*id.*  
 4 ¶ 37). However, the Amended Complaint acknowledges that after reviewing the very data that  
 5 plaintiffs criticize as “flawed” throughout their pleading, the FDA expressly “concluded that  
 6 adequate information has been presented to demonstrate that [Abreva] is safe and effective for  
 7 use as recommended in the agreed upon labeling text” – i.e., for “shorten[ing] healing time and  
 8 duration of symptoms.” (*Id.* ¶ 18; *see also* FDA Approval Letter at 1.)

9 Plaintiffs attempt to evade the broad scope of the FDCA’s express-preemption provision  
 10 by alleging that GSK’s marketing “exceeded the scope of the FDA’s approval” insofar as GSK  
 11 represented that Abreva can shorten the healing time of cold sores to “2 ½ days” and provides  
 12 symptomatic and anti-viral benefits for those who use the medication. (Am. Compl. ¶ 35.) These  
 13 efforts fail. The “2 ½ days” statement is based on data that the FDA considered prior to  
 14 approving Abreva for the purpose of shortening healing time and duration of symptoms (*see id.*  
 15 ¶¶ 15-19) and is therefore fully consistent with the FDA’s determination of safety and  
 16 effectiveness. *See Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 797 (2002) (“The  
 17 challenged statements on the [OTC lice] labels referring to the killing of lice do nothing more  
 18 than express in direct, straightforward, and easily understood language that which is implicit in  
 19 the mandatory labeling” and are “alternative explanations of the information” that the FDA  
 20 approved). And although plaintiffs allege that the FDA cautioned against marketing Abreva “as  
 21 an antiviral or as providing symptomatic relief of cold sores” (Am. Compl. ¶ 18), none of the  
 22 challenged marketing materials suggests that the medication provides such benefits, as discussed  
 23 above. In short, because plaintiffs’ claims challenge marketing that comports with the FDA’s  
 24 approved indication for Abreva, they are expressly preempted.

25 Finally, plaintiffs’ claims cannot be salvaged by the FDCA’s savings clause, which  
 26 provides that “[n]othing in this section shall be construed to . . . affect any action . . . under the  
 27 product liability law of any State.” 21 U.S.C. § 379r(e). Although the FDCA does not define  
 28 “product liability,” “[u]nder the product liability law of California, injury to the plaintiff from a

defective product is an essential element of a cause of action””; “if the damage consists solely of economic losses, recovery on a products liability theory is unavailable.” *Kanter*, 99 Cal. App. 4th at 790. Accordingly, putative class actions challenging the effectiveness of an OTC medication and claiming purely economic losses fall outside the scope of the savings clause. *See, e.g., id.* (holding that claims for breach of warranty and fraud in putative class action seeking to recover solely economic losses were outside the scope of the savings clause); *Carter*, 582 F. Supp. 2d at 1287 (following *Kanter* and holding that claims, including warranty causes of action, that do not seek damages for personal injuries, “are not actions for ‘product liability’ as defined under at least California law”); *see also In re Zantac*, 512 F. Supp. 3d at 1300 (noting that “[p]laintiffs have not demonstrated that product liability law in *any* state omits a requirement of injury to one’s person or property”). Plaintiffs’ lawsuit is precisely such an action because their theory of loss is that, as a result of GSK’s alleged misrepresentations and omissions, they have sustained “economic injuries.” (Am. Compl. ¶¶ 3-4.) In particular, plaintiffs seek to “recover full or partial refunds for Abreva . . . or . . . damages for the diminished value of the Product.” (*Id.* ¶ 211.) Because plaintiffs have not brought a “product liability” action under California law, their claims are preempted and should be dismissed for this reason as well.

#### IV. **PLAINTIFFS’ CLAIMS SHOULD BE DISMISSED WITH PREJUDICE.**

Finally, dismissal should be with prejudice because the defects set forth in this brief are not mere pleading failures; rather, they constitute fundamental deficiencies that cannot be cured by further amendment. *See Williamson v. Reinalt-Thomas Corp.*, No. 5:11-CV-03548-LHK, 2012 WL 1438812, at \*16 (N.D. Cal. Apr. 25, 2012) (“It would be futile to allow [p]laintiff leave to amend his complaint. As explained above, [p]laintiff’s claims fail not based on a deficiency in pleading, but rather because the theory regarding whether [d]efendants’ practices constitute actionable conduct is defective.”); *see also Rahman v. Greenpoint Mortg. Funding, Inc.*, No. 2:19-CV-530, 2019 WL 3550314, at \*4 (W.D. Wash. Aug. 5, 2019) (dismissing complaint with prejudice because “it is the legal insufficiency of [p]laintiff’s arguments that dooms his claims”). Moreover, Ms. Smith has already attempted to amend her complaint once in response to GSK’s first motion to dismiss, and it is clear that she simply cannot state valid claims. *See Williamson*,

2012 WL 1438812, at \*15-16 (granting motion to dismiss without leave to amend “even though this is the first court order dismissing the” lawsuit where plaintiff had previously amended complaint in response to a prior motion to dismiss, giving him multiple “bites at the proverbial apple”). Plaintiffs should not be given a third bite at the apple.

### CONCLUSION

For the foregoing reasons, the Court should dismiss plaintiffs’ Amended Complaint in its entirety with prejudice.

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Respectfully submitted,

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**FILER'S ATTESTATION**

I, Michael Minahan, am the ECF user whose identification and password are being used to file the foregoing document. In compliance with Civil Local Rule 5-1(i), I hereby attest that all signatories hereto concur in this filing.

/s/ Michael Minahan